Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTDC, NCI

Policy and Guidelines for
Accountability and Storage of Investigational Drugs

Policy:

FDA regulations require investigators to establish a record of the receipt, use, and disposition of all investigational agents. The NCI as a sponsor of investigational trials has the responsibility to assure the FDA that systems for drug accountability are being maintained by investigators in their clinical trial program. Investigators may delegate responsibility for drug ordering, storage, accountability and preparation to his/her designee. Note: According to FDA guidelines the investigator is ultimately responsible for all agents shipped in his/her name. The intent of drug accountability is to assure that DCTDC supplied agents are only used for patients enrolled on an approved DCTDC trial.

Guidelines for Drug Accountability and Storage:

- Drug disposition (drug receipt, transfer, dispensing or return) shall be maintained on the NCI Investigational Drug Accountability Record (attached). Alternative accountability records, either manual or electronic, may be used if include all the information required on the NCI Investigational Drug Accountability Record.

- A NCI Investigational Drug Accountability Record should be maintained at each location at which a drug is stored (e.g. main pharmacy, satellite pharmacy).

- DCTDC supplied investigational agents should be stored in a secure location which is only accessible to authorized personnel.

- Each drug should be stored and accounted for separately by protocol.

- There shall be a separate storage area and NCI Investigational Drug Accountability Record for each protocol, if same drug is used for more than one protocol.

- If a protocol uses more than one DCTDC supplied agent or more that one strength or formulation of the same agent, there shall be a separate storage area and NCI Investigational Drug Accountability Record for each agent, strength, and formulation.

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